Variation to a Registered Finished Pharmaceutical Product

Annual Notification

PLEASE NOTE THAT A SEPARATE APPLICATION SHOULD BE MADE FOR EACH FINISHED PHARMACEUTICAL PRODUCT (FPP).

Please complete each section of this application form electronically as a Word document and as a scanned signed PDF file. Please ensure that the electronic and the printed versions of the completed form accompany your submission.

## 1.1 Associated FPP name/NAFDAC Reg No:

*e.g. Dolutegravir Tablets 50mg – B4 - 2019*

## 1.2 Administrative details

Please note that the contact listed in the table below will be the local representative authorized by the FPP manufacturer (if different from the manufacturer) for communication for this specific application.

|  |  |
| --- | --- |
| **Applicant** |  |
|  |  |
| **Primary contact person responsible for this application** | Title:First name:Family name: |
| **Contact person's position** |  |
| **Contact person's postal address** |
| **Building/House No** |  |
| **Road/Street** |  |
| **Town/City** |  |
| **District/LGA** |  |
| **State** |  |
| **Postal code** |  |
| **Country** |  |
| **Contact person's email address** |  |
| **Contact person's phone number** |  |

If there are other contacts who should be routinely copied on correspondence for this application they should also be listed below.

|  |  |
| --- | --- |
| **Additional contact person**  | Title:First name:Family name: |
| **Contact person's position** |  |
| **Contact person's postal address** |
| **Building/House number** |  |
| **Road/Street** |  |
| **Town/City** |  |
| **District/LGA** |  |
| **State** |  |
| **Postal code** |  |
| **Country** |  |
| **Contact person's email address** |  |
| **Contact person's phone number** |  |

## 2. Summary of Annual Notification (AN) changes

|  |
| --- |
| **Summary of changes** |
| **Variation number and title** | **Pre-change details** | **Post-change details** | **Justification** **(Summary of studies performed to assess the effects of each change, if applicable)** | **Date of implementation** |
| *e.g. 31a - Change in the manufacturing process of the FPP (AN)* | *Instruction for passing of the slurry through 40 mesh is not included* | *At binder preparation stage, Instruction* *Included for passing of the slurry through 40 mesh.* | *To have lump free slurry* | *21 August 2017* |
|  |  |  |  |  |
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Note:

1. *For FPPs that have an agreed-upon Quality of Information Summary (QIS), the QIS should be revised and submitted with any revised sections highlighted.*
2. *When an annual notification involves a change in specifications or standard test procedures (STP) for an API or FPP, the signed and dated version of the revised specification and STP should be attached to the notification form, which should include a table of change history.*

## 3. Declaration

I declare that (Please check the appropriate declarations):

[ ]  For each change all conditions set out in the [*Guidelines on Variation to a Registered Pharmaceutical Product*](https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Guidelines/R_and_R_Guidelines/More_On_R_and_R/Guidelines-on-Variation-To-a-Registered-Pharmaceutical-Product-26373.pdf) are fulfilled.

[ ]  For each change all documents set out in the [*Guidelines on Variation to a Registered Pharmaceutical Product*](https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Guidelines/R_and_R_Guidelines/More_On_R_and_R/Guidelines-on-Variation-To-a-Registered-Pharmaceutical-Product-26373.pdf) are available for request.

[ ]  As a result of the changes notified, a revised specifications or standard test procedures (STP) are
 attached to this form.

[ ]  There is no change to the Quality Information Summary (QIS)

[ ]  A revised Quality Information Summary (QIS) is provided

[ ]  There are no changes being made other than those applied for in this submission, except for possible editorial changes. Any other changes will be applied for separately.

[ ]  The information submitted is true and correct.

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_